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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,516	09/08/2003	Francois Binette	022956-0225	7793

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EXAMINER	
QIAN, CELINE X	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 07/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/657,516	BINETTE ET AL.	
	Examiner	Art Unit	
	Celine X. Qian Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-47* is/are pending in the application.

4a) Of the above claim(s) *25-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-24* is/are rejected.

7)☒ Claim(s) *5* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0204,0604,0205*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-47 are pending in the application.

Election/Restrictions

Applicant's election of Group I in the reply filed on 5/9/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 25-47 are withdrawn from consideration for being directed to non-elected subject matter. Claims 1-24 are currently under examination.

Claim Objections

Claim 5 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5-14 and 17-24 are rejected under 35 U.S.C. 102(b)/(e) as being anticipated by Glorioso et al (US 6,413,511, IDS).

The claims are drawn to a genetically altered chrondrocyte that is used to express a therapeutic agent, and is effective to be delivered to a cell associated with a disorder and expresses a therapeutic agent to modify an environment surrounding the cell such that the chondrocyte is not structurally functional in the environment surrounding the cell.

Glorioso et al. disclose a chondrocyte that encodes a polypeptide of interest including interleukins, cytokines, tumor necrosis factors and biologically effective fragments thereof, which can be delivered to articular cartilage (see col. 27, lines 59-65, col. 21, lines 10-37). Glorioso also disclose that said chrondrocyte can be delivered with a gel matrix substrate to the damaged tissue site (see 29, lines 13-16). Glorioso further disclose that delivering a therapeutic agent to the damaged joint to treat arthritis (which can be an autoimmune disorder, see col. 27, lines 35-65). A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the intended use of the chrondrocyte does not impart a structural difference with what's disclosed in the prior art. Therefore, Glorioso et al. disclose the instantly claimed inventions.

Claims 1-3 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Bartholomew et al (Human Gene Therapy, 2001, Vol.12, pages 1527-1541, IDS).

Bartholomew et al. disclose human and baboon mesenchymal stem cells (MSC) that are genetically altered to express human EPO gene both *in vitro* and *in vivo* (see abstract).

Bartholomew et al. also disclose that said MSC can differentiate into chondrocytes *in vivo*. Therefore, Bartholomew et al. disclose the claimed chondrocyte that expresses a therapeutic agent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartholomew et al.

The teaching of Bartholomew is discussed above. However, Bartholomew does not teach a erythropoietin mimetibody as an therapeutic agent.

At the time of filing, the gene encoding epo has already been well characterized and its function ascribed to regions that bind to the corresponding receptor. It would have been obvious to one of ordinary skilled in the art to use such erythropoietin mimetibody to produce the same

therapeutic effect as full length epo. Such application would have been routine experimentation to an ordinary artisan. As such, there would have been reasonable expectation of success to generate a chondrocyte that expresses epo mimetibody and use it for gene delivery. Therefore, the claimed invention would have been *prima facie* obvious in view of the cited art.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claims 1 and 13, the term "a cell/region associated with a disorder" renders the claim indefinite because it is unclear what type of association applicants are referring to. In other words, it is unclear whether said cell/region is normal or diseased? Or is the cell involved in the pathogenesis of a disease? Further, the term "structurally functional" renders the claim indefinite because it is unclear what type of function Applicants are referring to. In other words, it is unclear how to determine whether a particular function of a chrondrocyte is related to a function. As such, the metes and bounds of the claim cannot be established. Claims 2-4, 6-12 and 14-24 are rejected because they depend on claims 1 and 13.

Regarding claims 2 and 14, the term "an agonist or antagonist of an antibody" renders the claims indefinite because it is unclear what type of agent Applicants are referring to. Does it

mean an antigen of an antibody, any agent that binds to the antibody, or any agent that blocks of the function of the antibody? Appropriate clarification is required.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X. Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Celine X Qian Ph.D.
Examiner
Art Unit 1636

CELINE QIAN, PH.D.
PRIMARY EXAMINER